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Analysis of reasons for medical malpractice litigation due to anterior cervical discectomy and fusion

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ABSTRACT

Background: Anterior cervical discectomy and fusions (ACDF) are among the most common cervical spine operations, with over 137,000 surgeries performed annually. Understanding reasons underlying malpractice pertaining to ACDF may inform physicians of practices to improve delivery of patient care and mitigate malpractice. The aim of our study was to analyze the causes and outcomes for lawsuits pertaining to ACDF.

Methods: The Westlaw Edge and Verdict Search databases were queried for malpractice claims utilizing the keywords "anterior cervical discectomy and fusion" and "ACDF". Inclusion criteria was based on relevance of case grievance(s) to ACDF. Data collected included date of case hearing, plaintiff demographics, defendant specialty, verdict ruling, location of filed claim, monetary award, and sustained injuries.

Results: Fifty cases were included in this study after excluding 1933 cases. Of the 50 cases, 34 (68%) resulted in a defendant outcome, 8 (16%) resulted in a plaintiff outcome, and 8 (16%) resulted in settlement. Plaintiff verdicts resulted in an average monetary payment of $9.70 million, while settlements resulted in an average payment of $2.06 million. Reasons for litigation were divided into 10 categories, most commonly improper postoperative management (20%), hardware failure (18%), intraoperative error (14%), off-label use of implants (14%), and insufficient informed consent (12%).

Conclusions: Malpractice claims due to ACDF are associated with higher frequencies of plaintiff verdicts and higher monetary costs compared to other spinal surgery procedures. There does not appear to be supporting evidence that spinal cord neuromonitoring is mandatory for ACDF procedures from a medicolegal standpoint.

1. Introduction

Compared to the 7% of physicians across all specialties who face malpractice claims, approximately 19% of neurosurgeons and 13% of orthopedic surgeons face a medical malpractice claim each year in the United States.[1] Within neurosurgery and orthopedic surgery, spine surgery precipitates the majority of filed malpractice claims.[2–4] Analysis of malpractice claims using commercial databases is performed across many specialties to offer practitioners insight into patients' values, methods to improve quality of care, and reasons that may cause a lawsuit for a given practice or procedure.[5–12]

Anterior cervical discectomy and fusion (ACDF) surgery is the most common cervical spine operation performed in the United States, with over 137,000 surgeries performed annually.[13] However, ACDF is not without considerable risks.[13–15] Understanding the reasons underlying malpractice claims pertaining to ACDF may help to inform practitioners of practices to improve delivery of patient care as well as mitigate malpractice. The aim of our study was to analyze the characteristics and

Abbreviations: **ACDF**, anterior cervical discectomy and fusion; **ANOVA**, one-way analysis of variance; **BMP**, bone morphogenetic protein; **INM**, intraoperative neuromonitoring; **SD**, standard deviation.

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reasons for lawsuits pertaining to ACDF through querying Westlaw Edge and VerdictSearch, two well-established legal databases widely used in medicolegal research.[3,5–12]

2. Methods

2.1. Data source

Two large databases—Westlaw Edge (Thomson Reuters, Eagan, MN) and VerdictSearch (ALM Media Properties, LLC, New York, NY)—were queried for medical malpractice cases filed between the years 1975 and 2022. While Westlaw is a consolidation of over 40,000 smaller legal databases and VerdictSearch comprises over 200,000 cases, neither are all-inclusive, and cases settled outside of the judicial system or before formal registration may not be included.[16] Thus, review of these databases provide insight into a representative sample rather than a comprehensive analysis of every ACDF-related lawsuit. These databases are still considered to be leading commercial providers for legal research within the professional legal community and have been extensively used for legal research in other medical specialties.[17–21] When evaluating for state-level data, state population sizes were obtained from the United States Census Bureau (https://data.census.gov/profile).

2.2. Data gathering

Querying Westlaw and VerdictSearch using the keywords "anterior cervical discectomy and fusion" and "ACDF" our search yielded 1160 and 823 results, respectively. Cases were reviewed and classified by two independent reviewers (HA & DB) based on the grievance(s) levied by the plaintiff. Discrepancies between reviewers were resolved by a third reviewer (WC) and a licensed attorney (PC). Cases were then deemed for inclusion based on whether or not the grievance(s) was directly related to ACDF. Inclusion criteria for case relevance were defined as a plaintiff's basis of litigation resting on a claim of medical malpractice due to ACDF. Data collection was performed using Microsoft Excel version 16.58 (Microsoft Corporation, 2022, Redmond, WA, USA). Additional data collected included date of case hearing, plaintiff sex and age, defendant specialty, verdict ruling, location of the filed claim, payment or settlement amount, and sustained injuries.

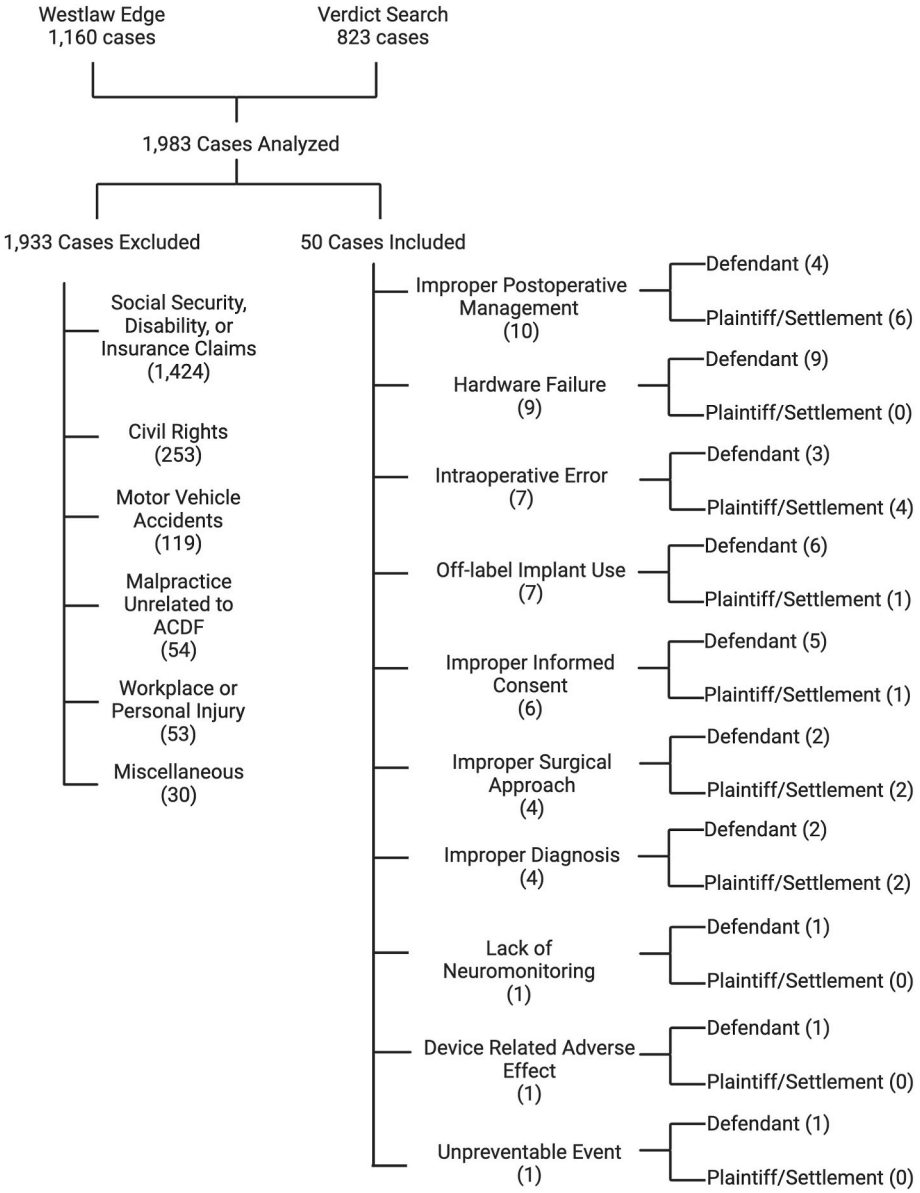

Fig. 1. Flow Diagram of the Case Review Process.

2.3. Statistical analysis

SPSS version 28 (IBM Corporation, 2021, Armonk, NY, USA) was utilized for all statistical analyses with statistical significance defined as $p < 0.05$. Descriptive statistics utilized means and standard deviations (SD) for case and demographic data. Homoscedasticity was assessed using homogeneity of variance tests and regression residual plots.[22] Q–Q plots and Kolmogorov–Smirnov tests were used to assess for normality of data.[23,24] To assess correlations among demographic and case data, Pearson's correlation tests were constructed. Differences based on plaintiff's sex and age were analyzed using independent sample *t*-tests with Levene's test for equality of variances. Pearson's Chi-squared test was used to identify differences for categorical variables. Case differences based on defendant specialty were analyzed using one-way analysis of variance (ANOVA) with Bonferroni and Tukey corrections.

3. Results

3.1. Case characteristics

The Westlaw and VerdictSearch databases returned a total of 1983 lawsuits satisfying the initial search parameters. A total of 50 cases were included in this study after exclusion of 1933 cases involving ACDF that were not specifically medical malpractice due to ACDF (Fig. 1). Of the 50 cases, 34 (68%) resulted in a defendant outcome, 8 (16%) resulted in a plaintiff outcome, and 8 (16%) resulted in a settlement. Of the 27 cases that disclosed defendant specialty, 16 (32%) were levied against neurosurgeons, 9 (18%) were levied against orthopedic surgeons, 1 (2%) was levied against a neurologist, and 1 (2%) was levied against a medical company representative. A total of 11 cases with a plaintiff-favorable verdict included defendant specialty. Of these, five were levied against orthopedic surgeons and four against neurosurgeons. Plaintiff verdicts resulted in an average monetary payout of $9.70 million (range: $.68 million – $22.37 million), while settlements resulted in an average payout of $2.06 million (range: $.92 million – $4.20 million). Of the 44 cases that disclosed geographic region in the United States, California (n = 3.9 cases/10 million persons), Texas (n = 3.05 cases/10 million persons), and Florida (n = 2.26 cases/10 million persons) had the greatest proportion of claims (Fig. 2). Table 1 describes the malpractice cases per defendant specialty, sex, and verdict ruling. The first case identified in our query was filed in the year 1987. From 1987 to 2022, the mean annual number of cases increased significantly, nearly doubling from an average of .79 cases per year to 2.06 cases per year (p = 00.0002).

3.2. Reasons for litigation

Reasons for litigation were divided into 10 categories (Table 2). Alleged improper postoperative management revolved around surgeon handling of postoperative complications and deemed insufficient postoperative follow-up. Alleged hardware failure was defined as litigation on the basis of injury following hardware breakage. Intraoperative error

Table 1
Description of malpractice cases due to ACDF.

Number of Cases per Outcome			Number of Cases per Specialty of Practitioner		
Outcome	n	n%	Overall Cases per Specialty		
Defendant	34	68.00%	**Specialty**	**n**	**n%**
Plaintiff	16	32.00%	Neurosurgeon	16	32.00%
Settlement	*8*	*50.00%*	Orthopedic Surgeon	9	18.00%
Plaintiff	*8*	*50.00%*	Misc	2	4.00%
Number of Cases per Plaintiff Sex			*Neurologist*	*1*	*50.00%*
Outcome	n	n%	*Physical Therapist*	*1*	*50.00%*
Male Plaintiff (n = 32)			Undisclosed	23	46.00%
Defendant	20	62.50%	**Neurosurgeon (n = 16)**		
Plaintiff	5	15.63%	**Outcome**	**n**	**n%**
Settlement	7	21.88%	Defendant	11	68.75%
Female Plaintiff (n = 17)			Settlement	4	25.00%
			Plaintiff	1	6.25%
Defendant	13	76.47%	**Orthopedic Surgeon (n = 9)**		
Plaintiff	3	17.65%	Defendant	4	44.44%
Settlement	1	5.88%	Plaintiff	4	44.44%
Undisclosed Plaintiff Sex (n = 1)			Settlement	1	11.11%
			Undisclosed (n = 23)		
Defendant	1	100.00%	Defendant	19	82.60%
Plaintiff	0	0.00%	Plaintiff	2	8.70%
Settlement	0	0.00%	Settlement	2	8.70%

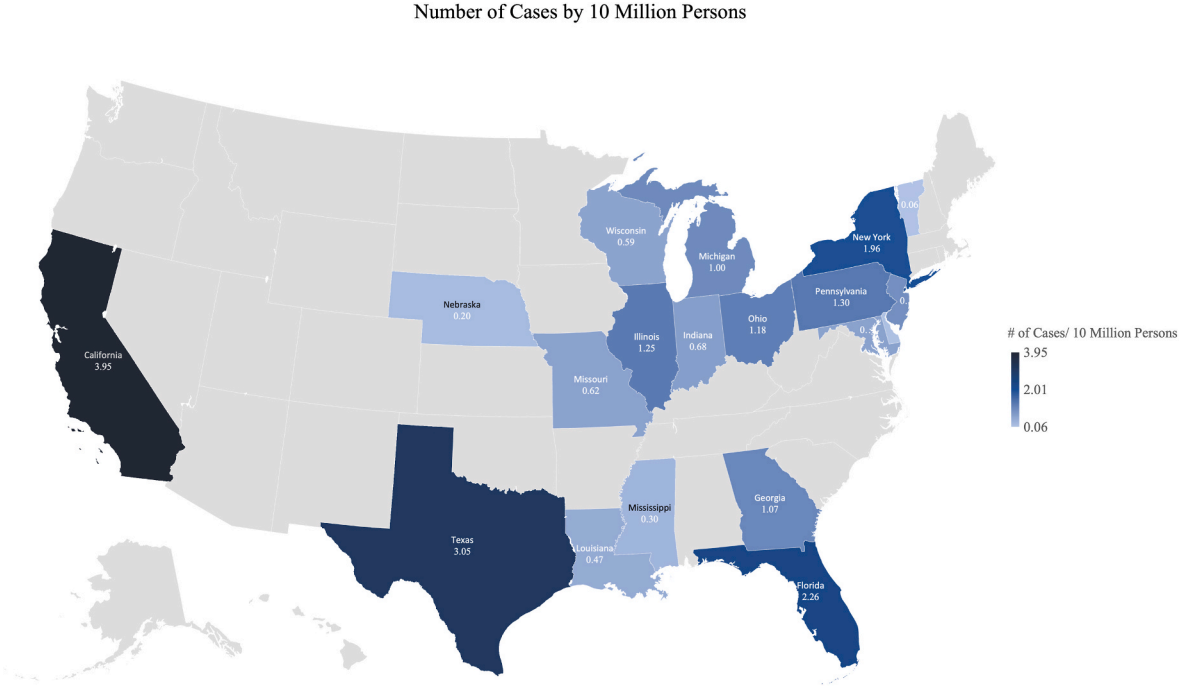

Fig. 2. Geographical Distribution of Included Cases per 10 Million Persons.

Table 2
Categorization of included cases per basis of litigation.

Basis of Litigation ($n = 50$)	Category Description
Alleged improper postoperative management (10)	Basis of litigation was injury due to alleged insufficient follow-up or management of postoperative complications
Postoperative epidural hematoma (4)	
Postoperative infection (2)	
Postoperative retropharyngeal hematoma (1)	
Postoperative hemorrhage (1)	
Postoperative medication overdose (1)	
Postoperative rehabilitation error (1)	
Alleged hardware failure (9)	Basis of litigation was injury due to failure of implanted hardware to perform as advertised
Bone screw failure (6)	
Cervical plate failure (3)	
Alleged intraoperative error (7)	Basis of litigation was injury due to preventable error on part of the practitioner during surgery
Negligent placement of hardware (3)	
Spinal cord injury (3)	
Nerve cord injury (1)	
Alleged off-label use of implants (7)	Basis of litigation was injury due to failure of implanted hardware to perform as advertised
Grafts with BMP (5)	
Artificial disc (2)	
Alleged insufficient informed consent (6)	Basis of litigation was alleged failure to obtain complete informed consent of risks, benefits, and details of surgery
Alleged improper surgical approach/level (4)	Basis of litigation was alleged incorrect or unnecessary surgery, surgery at the wrong level, or surgery from the wrong side
Alleged delay in diagnosis/ misdiagnosis (4)	Basis of litigation was negative outcome due to an alleged delay in treatment following injury
Alleged device-related adverse effect (1)	Basis of litigation was alleged side-effects from an experimental implanted cervical spine prosthetic device
Alleged lack of neuromonitoring (1)	Basis of litigation was a preventable nerve injury due to alleged lack of neuromonitoring during surgery
Alleged unpreventable event (1)	Basis of litigation was alleged injury after surgical lamp fell on patient during surgery

consisted of alleged preventable errors as a result of surgeon negligence including improper placement of hardware or spinal cord/nerve injury during the surgery. Off-label use of implants consisted of cases revolving around either the original use of implants in a manner outside of the official marketed use, or complications of surgery claimed to be due to implants used in an off-label practice. Insufficient informed consent cases were those were the plaintiff believed to have inadequate knowledge of the indications, risks, and details surrounding their operation. Improper surgical approach/level consisted of cases where the plaintiff alleged that the surgeon negligently performed the incorrect operation, or operated either at the wrong vertebral level or from the incorrect side. Delayed diagnosis and treatment was defined as cases where an alleged preventable injury occurred due to delays in receiving care. Three categories contained one case each and were as follows: (1) A device-related adverse event, where a subset of patients sustained an allergic reaction from the implanted device which did not fail in its intended use, (2) Lack of intraoperative neuromonitoring (INM) where the plaintiff affirmed that their injury would have been prevented through the use of INM, (3) and an unpreventable event where a surgical lamp fell atop the patient during the surgery (2%). The most common reasons were improper postoperative management (20%), hardware failure (18%) [bone screw failure (66%), cervical plate failure (33%)], intraoperative error (14%), off-label use of implants (14%) [grafts with bone morphogenetic protein (BMP) (71%), artificial disk (29%)], and insufficient informed consent (12%). Notably, an alleged lack of INM accounted for 2% of evaluated cases.

3.3. Damages sustained due to alleged negligence

Patient injuries and damages as a result of alleged practitioner negligence are outlined in Table 3. The most common complications claimed were pain and suffering (53%), need for reoperation (26%), catastrophic injuries (24%), and permanent weakness or motor/neurologic deficits (12%).

3.4. Case outcomes

Outcomes of litigation including verdicts in favor of defendant versus plaintiff and statistical significance were categorized by reason for litigation, result of negligence, and defendant specialty (Table 4). Cases were more likely to result in plaintiff outcome if the basis of litigation was alleged improper postoperative management ($p = 0.034$) or if the patient sustained a catastrophic injury (quadriplegia, paraplegia, brain injury, or death) as a result of alleged negligence ($p = 0.006$). Cases were more likely to result in a verdict for the defendant if the reason for malpractice claim was hardware failure (bone screw failure or cervical plate failure) ($p = 0.021$) or if the alleged negligence resulted in the patient's pain and suffering ($p < 0.01$).

4. Discussion

Spine surgery faces a greater proportion of malpractice lawsuits compared to all other surgical subspecialties.[2,25,26] Epstein et al found 42% of lawsuits involving cervical spine surgery arose from ACDF.[27] We sought to be the first study of its kind to describe the incidence and outcomes of litigation following ACDF procedures in the United States. The present study found that 68% of ACDF medical malpractice claims resulted in a defendant (physician) verdict, 16% resulted in a plaintiff verdict, and 16% resulted in a settlement. These findings are consistent with current literature trends evaluating medical malpractice outcomes, with defense rulings occurring in 54%–75% of overall spinal cases.[1,3,28–30] The proportion of defendant rulings in our study is lower than the national average for defendant rulings in medical malpractice of 75%, which may be attributable to the prevalence of catastrophic injury as a result of ACDF in comparison to other surgical procedures. Our findings demonstrated an average payout of $9.70 million for plaintiff verdicts, and an average payment amount of $2.06 million for cases settled out of court. These figures are markedly larger than those reported in other studies evaluating malpractice claims of spinal surgery as a whole.[1,3,28–30] Of the cases that included geographical location, the greatest proportion occurred in California, followed by Texas and Florida. This is in concordance with existing literature demonstrating that California is, per capita, amongst the most litigious state and experience disproportionately higher lawsuit volume and medical malpractice insurance premiums.[25] This may be attributed to a greater access to lawyers or to state tort laws that allow for more malpractice claims to be filed, such as the California Medical Injury Compensation Reform Act.[2,3,25]

The medical specialty of the provider was not associated with the

Table 3
Patient injuries or damages sustained as a result of Defendant's alleged negligence.

Plaintiff Injuries or Damages Claimed	n (%)
Pain and Suffering	16 (53%)
Reoperation	13 (26%)
Catastrophic Injury	12 (24%)
Quadriplegia	*5 (10%)*
Death	*3 (6%)*
Paraplegia	*2 (4%)*
Brain Injury	*2 (4%)*
Permanent Weakness or Neurologic Deficits	6 (12%)
Nerve Root Injury	3 (6%)

Table 4
Case outcomes per settlement, defendant, or plaintiff ruling.

Reason for Malpractice Claim	Defendant Verdict n (%)	Plaintiff Verdict or Settlement n (%)	*p*
Improper postoperative management	4 (8%)	6 (12%)	**0.034**
Hardware failure	9 (18%)	0 (0%)	**0.021**
Intraoperative error	3 (6%)	4 (8%)	0.136
Off-label use of implants	6 (12%)	1 (2%)	0.269
Failure to obtain informed consent	5 (10%)	1 (2%)	0.365
Improper surgical approach/level	2 (4%)	2 (4%)	0.421
Delay in diagnosis/ misdiagnosis	2 (4%)	2 (4%)	0.421
Device-related adverse effect	0 (0%)	1 (2%)	0.292
Lack of neuromonitoring	0 (0%)	1 (2%)	0.292
Unpreventable event	0 (0%)	1 (2%)	0.292
Result of Alleged Malpractice	**Defendant Verdict n (%)**	**Plaintiff Verdict or Settlement n (%)**	***p***
Pain and suffering	16 (32%)	0 (0%)	**<0.001**
Reoperation	11 (22%)	2 (4%)	0.124
Catastrophic injury	4 (8%)	8 (16%)	**0.006**
Permanent weakness or neurologic deficits	2 (4%)	4 (8%)	0.074
Nerve root injury	1 (2%)	2 (4%)	0.237
Defendant Specialty	**Defendant Verdict n (%)**	**Plaintiff Verdict or Settlement n (%)**	***p***
Neurosurgery	11 (22%)	5 (10%)	0.219
Orthopaedic Surgery	4 (8%)	5 (10%)	
Other/Not Disclosed	19 (38%)	6 (12%)	

verdict ruling ($p = 0.219$). Prior studies investigating spinal litigation outcomes report mixed findings on the impact of physician specialty, however. Daniels et al and Agarwal et al found no significant correlation between practitioner specialty and case outcome.[3,30] Park et al found cases levied against neurosurgeons to be more likely to result in a plaintiff favorable outcome while Mani et al found that cases against orthopedic surgeons to be linked to higher compensation plaintiff payments.[1,29] While we found a greater number of cases with plaintiff favorable verdicts to name an orthopedic surgeon as the primary defendant ($n = 5$) as compared to neurosurgeons ($n = 4$), we cannot draw any significant conclusions due to the limited sample size.

In the 50 cases examined, catastrophic complications (death, quadriplegia, paraplegia, and anoxic/hypoxic brain injury) ($p = 0.006$) and alleged improper management of postoperative complications were associated with a plaintiff verdict ($p = 0.034$). Improper postoperative management, including postoperative care of epidural hematomas or postoperative infection, and hardware failure, most commonly bone screw failure, were the most cited reasons for litigation following ACDF. Unlike prior spinal malpractice studies, we found that cases citing improper postoperative ACDF management were correlated with an increased likelihood of a plaintiff verdict or settlement ($p = 0.034$).[1] As the accepted risks of ACDF include epidural hematomas, postoperative wound infections, nerve palsies, and instrument failure, it may be more difficult for a plaintiff to demonstrate medical malpractice as the direct cause of these postoperative complications, however, it is the surgeon's responsibility to provide proper follow-up and timely treatment of any complications that may arise.[13,14] Our study demonstrates that an alleged failure to do so is associated with a greater likelihood of a plaintiff verdict. Alleged hardware failure ($p = 0.021$) and patient pain and suffering ($p < 0.001$) were significantly associated with a defendant ruling. This observation may be due to the fact that pseudoarthrosis or unsuccessful arthrodesis are well-known complications following fusion surgery and therefore may be easier to defend in court. Similarly, a patient's postoperative pain and suffering, without neurological complications, may be difficult to attribute to a surgeon's negligence or as a result of the operation as a whole. While permanent weakness or neurologic deficits approached statistical significance ($p = 0.074$), our findings did not demonstrate a significant association between permanent weakness or neurologic deficits and litigation outcome. Unlike prior studies, we did not find a statistically significant correlation between litigation outcome and delayed diagnosis ($p = 0.421$), informed consent ($p = 0.365$), or intraoperative error ($p = 0.136$).[1,3,7,31] However, it is possible a larger sample size may have pushed these findings to statistical significance.

The benefits of using INM during ACDF is debated in the current literature and no universal guidelines to dictate the indications for the use of INM currently exist.[32–36] INM is associated with considerable financial burden, but has not been shown to be successful in improving patient outcomes—further calling into question its utility in spinal cases.[32,35–38] Bible et al found that medicolegal concerns were the main reasons for choosing to use INM.[32] However, our study revealed only one case levied on the basis of alleged lack of INM, which resulted in a defendant verdict. As such, a surgeon's decision to employ neuromonitoring during ACDF surgeries should be based on patient-specific factors and local, accepted standards of care rather than medicolegal pressure.

Failure to obtain sufficient informed consent is one of the most common bases of litigation in spine malpractice, with prior studies evaluating medical malpractice surrounding cervical spine surgery identifying perceived insufficiently informed consent as a basis of litigation in over 50% of cases.[1,2,39,40] Similarly, our findings demonstrate improper informed consent and patient-physician communication as the basis of almost a quarter of total cases. This not only highlights the importance of physician and patient communication, but also identifies a viable source of defensive medicine and malpractice prevention. A study by Taiwo et al found that issues of consent are common causes of formal complaints and litigation, suggesting that a standardized consent process, employing objective measures where possible, may help reduce this burden.[41] Park et al found insufficient informed consent to be strongly correlated with defendant verdict, which could be due to the difficulty in proving failure to provide informed consent in a legal setting.[1] Todd et al offer a checklist that spine surgeons may follow during preoperative discussions in order to provide a concrete structure that could later be presented during a court trial.[42] This checklist builds upon established practices including describing the pathology requiring treatment, the natural history of the condition if untreated, the details of the recommended surgery, as well as its benefits and risks. Todd et al emphasize potential alternatives to operating and understanding the patient's expectations of the treatment.[42] While current informed consent discussions typically focus on risks and potential adverse outcomes associated with the surgery, greater emphasis on alternative treatment options and the implementation of multimodal educational tools such as videos and pamphlets may serve to improve preoperative conversations, minimizing the risk of malpractice claims and ensuring that patients are better informed.

The off-label use of bone implants (devices and grafts with BMP) was included in a considerable portion of cases alleging hardware failure as the basis of litigation. Our findings did not reveal an increased likelihood of a plaintiff ruling ($p = 0.269$) despite studies implicating BMP in increased complication rates when used in the cervical spine.[43–45] This may be due to the well-documented complication rates associated with BMP as well as its benefits in cervical fusion.[43–46] Of note, one case resulting in a defendant verdict was filed after a surgical light fixture, improperly secured by maintenance staff during operating room renovation, fell down onto the patient during surgery.

Taken all together, this study suggests that, despite a surgeon's best efforts to provide competent care, there exist instances where litigation may be unavoidable. However, significant preventable causes of litigation include the insufficient postoperative monitoring of expected complications and insufficient informed consent. Thus, it is important to keep in mind the necessity of close follow-up monitoring of all

postoperative complications and the importance of thorough medical charting and transparent communication with patients in order to both improve patient outcomes and reduce the risk of patient–physician conflict and potential legal action.[47]

4.1. Limitations

This study is not without several limitations. This retrospective study utilized the Westlaw and VerdictSearch databases. When using such databases, there is a potential for selection bias as cases are reported voluntarily and may not include cases that were concluded prior to trial, including those settled privately, deemed "frivolous" without substantial grounds, or grossly negligent and not defensible. Although the use of both databases provides a more encompassing view of the medicolegal landscape than either one alone, this by no means entails a comprehensive medical malpractice review and cannot be used to assess the prevalence of all ACDF related lawsuits. It is estimated that 72% of malpractice claims are dropped, denied, or dismissed prior to trial or settlement.[48] As such, many malpractice claims will not be accessible in legal databases because they are not part of formal judicial registration. Thus, the cases included in this study should be considered as a representative sample of all malpractice claims pertaining to ACDF. Furthermore, not all court documents contained detailed patient medical histories, which limited the depth of our data insight. Correspondingly, the intricacies of medical terminology and granularity of detail varies on a case-by-case basis. Despite these limitations, Westlaw and VerdictSearch are two of the most widely used sources for medical malpractice claims research in the absence of a single, comprehensive database of all malpractice claims.

5. Conclusions

Malpractice claims due to ACDF are associated with higher frequencies of plaintiff verdicts and higher monetary costs compared to other spinal surgery procedures. Our findings demonstrate that improper management of postoperative complications and catastrophic complications—including death, significant paralysis, or brain injury—are associated with plaintiff verdicts, while hardware failure and patient pain and suffering are associated with defendant rulings. There does not appear to be supporting evidence that spinal cord neuromonitoring is necessary for ACDF procedures from a medicolegal standpoint.

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CRediT authorship contribution statement

Haad Arif: Data curation, Writing – original draft, Writing – review & editing. **Jacob Razzouk:** Writing – original draft, Writing – review & editing. **Daniel Bohen:** Data curation, Writing – original draft, Writing – review & editing. **Omar Ramos:** Conceptualization, Formal analysis, Supervision, Writing – review & editing. **Olumide Danisa:** Conceptualization, Supervision, Validation, Writing – review & editing. **Paul Cheng:** Writing – review & editing. **Wayne Cheng:** Conceptualization, Supervision, Validation, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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